#### **REMARKS**

Claims 51-110 are pending in the present application for the Examiner's consideration. Reconsideration and allowance of the present application in view of the following remarks are respectfully requested.

# A. The Specification

Pursuant to the Examiner's request, the specification has been checked to determine the presence of possible minor errors. At this time, Applicant is unaware of any errors that require correction.

### B. The Claim Rejections Under 35 U.S.C. § 102(a) Should Be Withdrawn

Claims 51-53, 60-61, 64-65, 69-70, 76-77, 79-83, 90-91, 94-95, 99-100, 106-107 and 109-110 were rejected under 35 U.S.C. § 102(a) as being anticipated by United States Patent No. 5,464,650 to Berg et al. ("Berg") for the reasons set forth on pages 2-3 of the Office Action. Applicants respectfully traverse.

More specifically, Berg discloses a stent having a coating containing a polymer and a therapeutic substance or drug. (See e.g., Abstract). The drug is released by elution from the coating. (Col. 3, lines 14-22; Abstract)). The coatings disclosed in Berg contain an elutable drug throughout the coatings. Berg does <u>not</u> disclose a coating or coating portion that is free of an elutable drug. (See e.g. col. 2, lines 44-47; col. 5, line 43-col.7, line 15).

Berg does not anticipate the present claims because Berg fails to disclose each and every recitation of the present claims. For instance, Berg fails to disclose or suggest a coating comprising (1) an undercoat comprising a polymeric material and a biologically active material, such as a drug, and (2) a topcoat overlying the undercoat. Also, Berg fails to teach or suggest a topcoat or any portion of a coating that is substantially free of an elutable material. In fact by teaching that the coatings contain an elutable drug throughout the coatings, Berg teaches away from a coating having a topcoat that is substantially free of an elutable material. Therefore, Berg does not disclose or suggest the present invention. Thus, the rejection based on Berg should be withdrawn.

Furthermore, the Examiner states that U.S. Patent No. 5,492,895 to Vlasuk *et al.* ("Vlasuk") shows that persons of skill in the art were aware of therapeutic substances that inherently inhibit smooth muscle cell proliferation. (Office Action at page 3). It should be

noted that Vlasuk does not remedy the deficiencies of Berg. In particular, Vlasuk does not even disclose a stent and therefore does not disclose or suggest a stent having the coating recited in the present claims.

## C. The Claim Rejections Under 35 U.S.C. § 103(a) Should Be Withdrawn

Claims 54-59, 62-63, 66-68, 71-75, 78, 84-89, 92-93, 96-98, 101-105 and 108 were rejected under 35 U.S.C. § 103(a) as being obvious over Berg in view of United States Patent No. 5,288,711 to Mitchell et al. ("Mitchell") for the reasons set forth on page 3 of the Office Action. Applicants respectfully traverse.

As discussed above, Berg does not disclose or suggest the presently claimed invention. Mitchell does not remedy the deficiencies of Berg. Mitchell describes a method of preventing or treating hyperproliferative vascular disease in a mammal by administering an antiproliferative effective amount of a combination of rapamycin and heparin to the mammal. These drugs can be administered orally, parenterally, intravascularly, intranasally, intrabronchially, transdermally, rectally, or via a vascular stent impregnated with a combination of rapamycin and heparin.

However, Mitchell does not make any mention of a coating disposed upon a stent. Since Mitchell does not teach a coating disposed on a stent, Mitchell does not disclose or suggest the stent coating of the present invention. Thus, since neither Mitchell nor Berg, whether taken singly or collectively, renders the presently claimed invention unpatentable, the rejection based on the combination of Berg and Mitchell should be withdrawn.



# **CONCLUSION**

All claims are believed to be in condition for allowance. Furthermore, Applicants respectfully request an interview with the Examiner. The undersigned attorneys for Applicants will contact the Examiner to arrange for an interview to accelerate the allowance of the present application. No fee is believed to be due for this amendment. Should any fee be due, please charge the required fee to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

Date: September 21, 2004

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